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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,401	06/25/2003	Stephen R. Hanson	18852-002002 / 5202B	3459

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EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 01/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/603,401	HANSON, STEPHEN R.	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 50-61 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 50-61 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6-25-03, 9-13-05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendment and Information Disclosure Statement, filed 6/25/03 and Information Disclosure Statement filed 9/18/05 are acknowledged.

Claims 1 – 49 have been cancelled. The specification has been amended to reflect the status of the parent application. Claims 50 – 61 are pending in this action.

Double Patenting

Claims 50, 53 – 60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 3, 5 – 7, 13 – 15 of copending Application No. 11/127544. Although the conflicting claims are not identical, they are not patentably distinct from each other because while copending claims do not recite the length of time for which the composition must effect release of the drug, it would be obvious to the artisan to deliver the drug for a length of time appropriate to treat the condition of interest, and the artisan would be able to judge what this length of time is.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 50 –53 and 55 – 61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a written Description Rejection**.

Claim 50 recites an agent that reduces platelet counts in a subject. This is a very broad genus. While the specification describes certain species of this genus (see specification page 18), this disclosure is not sufficient to provide written description for the entire genus. The artisan would recognize that Applicant had possession of a composition comprising any species of the entire genus of agents that reduce platelet count as of the time of the invention based on this disclosure.

The remaining claims are rejected because of their dependence on claim 50, thus incorporating the same subject matter that is inadequately described therein.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 52, and 54 – 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 52 recites the limitation "agent for treating vascular disease" in claim 50. There is insufficient antecedent basis for this limitation in the claim. It is presumed that Applicant intended claim 52 to depend on claim 51. Clarification is requested.

Claim 54 recites "a derivative of anagrelide". The claim is indefinite since the artisan would not be certain what constitutes a derivative or anagrelide, and accordingly would not understand the metes and bounds of the claim. Clarification is requested.

Claims 55 and 56 recite amounts of agent to be released, wherein the amount of agent is either 30 g/kg/day to 150 g/kg/day or 1 g/kg/day to 150 g/kg/day. For a person who weighs 80 kg, this means that up to 12,000 g or 12 kg of agent would be released per day. This is likely to be a lethal dose. Also, for the agent to be released over at least seven days, the device would have to comprise at leas 84 kg of agent. This does not seem plausible. Clarification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 50 – 53 and 55 – 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindahl et al., US 6,083,518.

Lindahl discloses compositions for the release of drugs, such as busulphan (claims 1, 10, abstract). It is noted that busulphan is admitted by applicant to be a compound that reduced platelet count in a subject (specification page 18). Lindahl discloses that a significant advantage of such compositions is the ability to easily control the rate and duration of release of the active agent (col. 2 lines 62 – 67, col., 7, lines 19 – 38).

Accordingly, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to make a composition comprising busulphan that is released over any amount of time, and at any rate. The motivation to do so is to effectively treat a subject who needs to be treated with busulphan over a period of time. The artisan would know how long the treatment should last and would also know the appropriate dosing regimen, which would vary from subject to subject depending on factors such as age, weight, physical condition, medical condition being treated, gender, and other factors understood by the artisan. The artisan would be motivated to optimize these parameters in order to effectively treat the patient. With regard to claims 51 and 52, the artisan would recognize that pain is associated with many diseases, and that aspirin is useable to treat pain. Accordingly, the artisan would be motivated to include aspirin in the device order to decrease the pain of the subject. Aspirin qualifies as an agent for treating vascular disease, as specified in claims 51 and 52.

Since combining drugs and optimizing dosage are within the purview of the artisan, the artisan would have a reasonable expectation of success. The expected result would be a sustained release composition according to Lindahl which released the active agent over appropriate times and in appropriate amounts, and which also comprised aspirin.

Claims 50 – 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flemming et al., U 4,432,980, of record.

Flemming discloses compositions of anageride and acetyl salicylic acid (abstract, col. 3, lines 4 – 11, col. 4 lines 45 – 54). Flemming discloses that such compositions

have supra-additive pharmaceutical effects (abstract). Flemming further discloses that such compositions preferably contain both drugs in one integral unit (col. 5, lines 40 – 53), and that these compositions are useful for long term treatment or prophylaxis (col. 5, lines 54 – 67).

Flemming does not teach sustained release compositions.

Nonetheless, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to make a sustained release composition comprising anagerlide and acetyl salicylic acid. The motivation to do so is that such compositions are useful for long term prophylaxis. As such, in order to facilitate easy long term-treatment, the artisan would find it obvious to make a composition that could release these agents over long periods of time, such as greater than seven days, greater than 30 days, greater than 6 months, greater than 1 year, and greater than 5 years. With regard to the dosing, the artisan would find it obvious to use the appropriate dosing to treat the condition of interest. Flemming provides some guidance to assist the artisan in doing this.

The expected result would be a sustained release device comprising anagerlide and acetyl salicylic acid, which delivered the drugs over long periods of time, such as greater than seven days, greater than 30 days, greater than 6 months, greater than 1 year, and greater than 5 years, wherein the devices had an effective dosage of the drugs. Since Applicant admits that the making of these types of devices is well known in the art, the artisan would enjoy a reasonable expectation of success.

Conclusion

No claims are allowed. No claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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